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CLINICAL TRIAL REPORT

Anti-Acne Efficacy Evaluation of *Sebuma* Azelin 40 on Subjects with Mild to Severe Acne

STUDY DETAIL:

Study Type	Clinical Trial
Study Center	20 King Street, Rockdale NSW 2216 Australia
Study Number	318-DKM-BTU-19-07
Study Start Date	August, 2019
Actual Study Completion Date	November, 2019

CLIENT INFORMATION:

Client Name	Pars Hayan Laboratories
Client address	No. 54, West Atefi Ave, Nelson Mandela Blvd, Tehran, Iran.
Samples Received on	July 2019

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STUDY DESIGN:

Official Title	A 2-week, Randomized Study Analyzing the Clinical Efficacy of **"*Sebuma* Azelin 40"** (Azelaic Acid 20%, Salicylic Acid, Mandelic Acid, Lactic Acid) in Patients with Mild to Severe Acne
Actual Enrollment	10 participants
Primary Purpose	Treatment
Ages Eligible for Study	18 Years to 35 Years (Adult)
Sexes Eligible for Study	All
Studied product	*Sebuma* Azelin 40
Active Ingredients in Product	**Primary Actives:** Azelaic Acid 20% Salicylic Acid Mandelic Acid Lactic Acid **Secondary Active:** Aloe Vera Gel
Application Method	Qualified subjects will apply a few drops to affected areas of cleansed and dried skin at night. Leave on for approximately 2-8 minutes, depends on skin condition and its sensitivity. Then rinse with lukewarm water. Subjects apply the product for a period of 2 weeks and will be required to return to the doctor's office for up to 3 visits.

CRITERIA:

To be included in the study, participants have the following criteria:

- Predominantly facial localization of acne
- Mild to moderate acne vulgaris characterized by the presence of both inflammatory papules and/or pustules, and comedones (whiteheads/blackheads).
- Male and female patients
- Age greater or equal to 18 years
- Ability and willingness to accept and comply with the administration of the investigational drugs over 12 weeks and to comply with the required medical examinations.

EXCLUSION CRITERIA:

To be included in the study, participants should not have the following criteria:

- Anticipated or scheduled hospitalization, e.g. for surgery, during the study
- Moderate or severe acne requiring systemic therapy
- History of hypersensitivity to any ingredient of the trial drugs

RESTRICTIONS:

participants must not have taken or have had the following types of treatment or therapy prior to being admitted into the study:

- Oral isotretinoin (i.e. Accutane) for 6 months
- Ortho Tri-Cyclen or Estrostep for 3 months
- Oral antibiotics (i.e. tetracyclines, erythromycin) for 4 weeks
- Systemic corticosteroids for 4 weeks
- Systemic non-steroidal anti-inflammatory drugs (NSAIDs) at anti-inflammatory doses for 4 weeks
- Topical (applied to skin) retinoid creams, ointments, gels for 2 weeks
- Topical antibiotics (i.e. tetracyclines, erythromycin, clindamycin) for 2 weeks
- Topical corticosteroids or topical non-steroidal anti-inflammatory (NSAIDs) drugs for 2 weeks
- Topical imidazole antimycotics for 2 weeks
- Topical benzoyl peroxide (BPO) for 2 weeks
- Topical over-the-counter remedies for acne (salicylic acid) for 2 weeks If you have had any of the above, you may still qualify for the study following a washout period (time for your body to completely eliminate, or get rid of, the medication). The study doctor will evaluate whether there is anything else in your history that may affect your safety in the study or interfere with evaluations. He/she may therefore advise you not to participate.

PROCEDURE AND EXPERIMENT:

Investigator's assessment of subject's acne condition using a score of 0 (best) and 5 (worst) based on **lesion counting technique of Cook's photographic method.**

Lesion counting involves recording the number of each type of acne lesion and determining the overall severity. It is defined as the total number of comedones and inflammatory lesions.

SCORE SYSTEM BASED ON COOK'S PHOTOGRAPHIC METHOD:

Condition	Score	Description
Clear	0	The comedones are treated
Very Mild	1	Easily recognizable; less than half the face is involved.
Mild	2	
Moderate	3	More than half of the face is involved.
Severe	4	Entire face is involved.
Very Severe	5	

participants	First Condition	First Visit	Second Visit	Third Visit	Result
1	Very Mild	Clear			0
2	Very Severe	Severe Score: 4	Mild Score: 2	Very Mild Score: 1	Improved
3	Moderate	Moderate Score: 3	Clear		0
4	Moderate	Moderate Score: 3	Mild Score: 2	Clear	0
5	Mild	Very Mild Score: 1	Clear		0
6	Mild	Mild Score: 2	Very Mild Score: 1	Clear	0
7	Severe	Severe Score: 4	Moderate Score: 3	Mild Score: 2	Improved
8	Moderate	Mild Score: 2	Clear		0
9	Severe	Moderate Score: 3	Very Mild Score: 1	Clear	0
10	Moderate	Moderate Score: 3	Mild Score: 2	Clear	0

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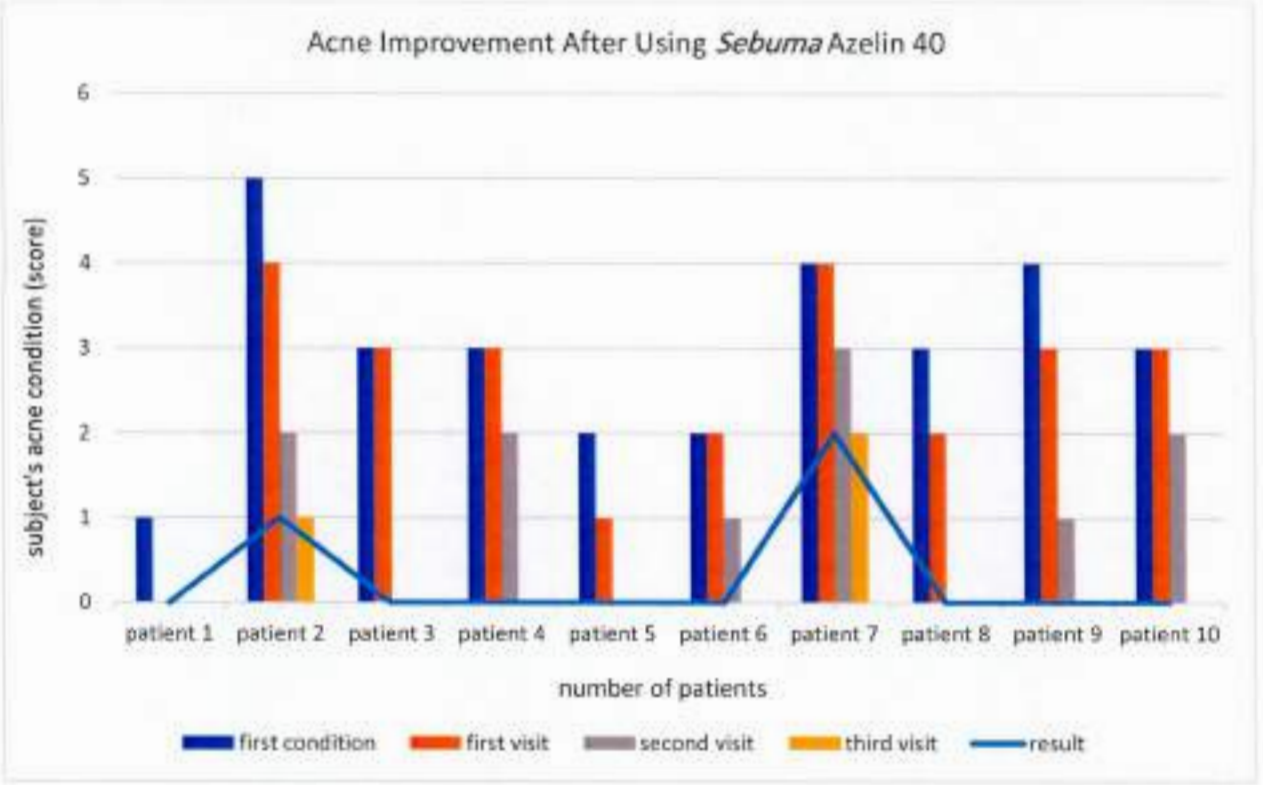

Result and Conclusion:

This study evaluated the efficacy of a 2-week treatment using combination of Azelaic Acid 20%, Salicylic Acid, Mandelic Acid and Lactic Acid in patients with mild to severe facial acne. Azelaic Acid is a naturally occurring dicarboxylic acid and acts as a comedolytic, antimicrobial, and anti-inflammatory agent. The results of clinical study under dermatological control of *Sebuma* Azelin 40 topical treatment indicate significant reduction in the total lesion number and size of acne and inflammatory lesions. Moreover, it effectively eliminates blemishes and imperfections compared to baseline which lead to the improvement of overall skin condition.

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